UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

MIESHA MCINTYRE, individually and on behalf of all others similarly situated, Plaintiff, vs. KENVUE, INC. AND MCNEIL CONSUMER HEALTHCARE, Defendants.	Case No. _____ **CLASS ACTION COMPLAINT** **JURY TRIAL DEMANDED**

COMES NOW, MIESHA MCINTYRE ("Plaintiff"), individually and on behalf of the Class, who states and alleges as follows:

INTRODUCTION

1. Plaintiff brings this action on behalf of herself and on behalf of a Class of similarly situated consumers who purchased products to be taken orally containing phenylephrine, a compound that purportedly acts as a decongestant, but does no such thing according to the U.S. Food and Drug Administration. *See* Exhibit 1. The over-the-counter product Sudafed PE ("Product") contains phenylephrine and was manufactured, distributed, marketed, and sold by Defendants as an effective nasal decongestant. The Product's lack of efficacy was not disclosed to Plaintiff prior to Plaintiff's purchase of the Product and Plaintiff would not have purchased the Product or would have paid less for it had she known the Product did not work as advertised.

2. Phenylephrine and pseudoephedrine are two compounds found in nasal decongestants. Products containing phenylphrine are available to consumers over the counter without a prescription or asking a pharmacist. The FDA requires products containing pseudoephedrine to be sold behind the pharmacy counter because they can be used to produce

methamphetamine. Therefore, products containing phenylphrine have become the nasal decongestant of choice for consumers because it is easy to obtain.

3. Phenylephrine is found in many over the counter oral medications that purportedly act as decongestants, including such popular products such as Mucinex, Tylenol Cold & Flu, Benadryl, Theraful, Nyquil and Sudafed Products produced by Defendants Kenvue and McNeil Consumer Healthcare).

4. Unknown to ordinary consumers like Plaintiff, but known to the manufacturers in this lucrative market, phenylephrine taken orally is ineffective. It provides no relief for congestion, and is no better than a placebo, like a sugar pill, as a decongestant when taken orally.

5. Had Plaintiff known that the phenylephrine-containing Products were entirely ineffective as a nasal decongestant, she would not have purchased them, or would have paid substantially less for them. Plaintiff, and the class members define herein, purchased the Products in reliance on Defendants' false and deceptive marketing claims. As a result of Defendants' false and deceptive marketing, Plaintiff, and the class members, suffered economic damages, including the cost of purchasing the Products.

6. Accordingly, Plaintiff, on behalf of herself and all other consumers of Defendants' phenylephrine products, seeks to hold Defendants accountable for their deceptions, breaches of warranties, and violations of Minnesota consumer protection statutes.

PARTIES

7. Plaintiff is a resident of the City of Brooklyn Center, County of Hennepin, Minnesota.

8. In and around September 2023, Plaintiff had sinus congestion associated with a cold and purchased Sudafed PE, a product manufactured by Defendants and containing

phenylephrine for purported decongestant relief. The Product was ineffective in relieving Plaintiff's congestion.

9. Defendant Kenvue Inc. is an American consumer health company, and formerly the consumer healthcare division of Johnson & Johnson. Kenvue is headquartered in Skillman, New Jersey. It wholly owns Defendant McNeil Consumer Healthcare. On information and belief, all assets and liabilities associated with the Decongestant Products that had been manufactured, marketed, and/or sold by Johnson & Johnson are now owned by Defendant Kenvue.

10. Defendant McNeil Consumer Healthcare is wholly owned by Defendant Kenvue, with headquarters in Fort Washington, Pennsylvania. McNeil manufactures and markets numerous Decongestant Products, including but not limited to Sudafed PE, a purported decongestant containing phenylephrine.

JURISDICTION AND VENUE

11. This Court has original jurisdiction of this action under the Class Action Fairness Act of 2005. Pursuant to 28 U.S.C. §§ 1332(d), this Court has original jurisdiction because the aggregate claims of the members of the putative class exceeds $5 million, exclusive of costs, and at least one of the Class members is a citizen of a different state than Defendant.

12. This Court has supplemental jurisdiction over the state law claims pursuant to 28 U.S.C. § 1367 because all other claims that are so related to claims in the action within such original jurisdiction that they form part of the same case or controversy.

13. Defendant regularly and systematically conducts business and sells its products in this District to customers in this District, including to Plaintiff and the Class. As such, Defendant is subject to the jurisdiction of this Court.

14. Venue is likewise proper in this district pursuant to 28 U.S.C. § 1391 because Defendant is subject to personal jurisdiction in this District and regularly conduct business in this District.

FACTUAL ALLEGATIONS

15. In September 2023, the FDA held a Non-prescription Drug Advisory Committee ("FDA NDAC") meeting to discuss the effectiveness of oral phenylephrine ("PE") as an active ingredient in over-the-counter cough and cold products that are indicated for the temporary relief of congestion, both as a single ingredient product and in combination with other ingredients.

16. The FDA NDAC committee discussed new data on the effectiveness of oral phenylephrine and concluded that the current scientific data do not support that the recommended dosage of orally administered phenylephrine is effective as a nasal decongestant.

17. Studies examining the efficacy of oral phenylephrine in subjects with season allergic rhinitis demonstrated:

a. that PE is no more effective than placebo in decreasing nasal congestion;

b. additional plasma concentration data from published pharmacokinetic studies are consistent with a lack of efficacy due to PE having low oral bioavailability;

c. lack of clinically important adverse effects on blood pressure at the doses evaluated in these pharmacokinetic studies are consistent with a lack of efficacy;

d. because *in vitro* data show the nasal vasculature in man and the pig are less sensitive to PE than the extranasal vasculature, there is no pharmacological basis for oral PE to alleviate symptoms of nasal congestion without attendant peripheral side effects.

18. In 2007, the FDA approved PE, based on the information available at the time, that PE could be considered an effective oral nasal decongestant.

19. Notably, the Original Cough-Cold Advisory Panel noted that the data "were not strongly indicative of efficacy," and in the absence of a safety concern, the Panel recommended that the Agency categorize oral PE (immediate release hydrochloride salt) as safe and effective for use as an orally administered nasal decongestant at an adult/adolescent dosage of 10 mg administered every 4 hours.

20. In 2023, the FDA NDAC reviewed its prior 2007 Generally Recognized as Safe and Effective (GRASE) classification of PE and approval of PE as an over the counter medication due to new studies since its 2007 conclusion.

21. The FDA NDAC conducted a rigorous and scientific analysis of the new data since the 2007 decision.

22. Data from three large, adequately controlled clinical trials conducted subsequent to the 2007 NDAC meeting are consistent with prior data: they demonstrate a lack of efficacy with oral PE.

23. Merck conducted two trials in subjects with allergic rhinitis and Johnson and Johnson conducted a trial in subjects with colds. All used clinically acceptable designs and nasal congestion symptom scores as primary endpoints. These three trials represent by far the largest and most carefully constructed trials that have ever been performed to evaluate the decongestant effect of oral PE. None of the three demonstrated any efficacy compared with placebo.

24. In describing these three trials, the FDA NDAC stated: "We believe that these new clinical pharmacology and clinical data are consistent, substantial, and believable, and they confirm that orally administered PE is not effective at any dose that can be developed and still provide a reasonable margin of safety."

25. The FDA NDAC reviewed the data that supported the prior 2007 GRASE determination and found that the original studies suffered from "significant methodological and statistical issues with the design and conduct of the original studies."

26. The FDA NDAC concluded:

> As a result of our evaluation, we believe that the new efficacy data far outweigh the data provided to the Agency as part of the original Panel review. These results suggest that: 1) oral PE at monographed dosages is not effective as a decongestant (i.e., in the face of the new data, the original data are likely not sufficient to support a GRASE determination), 2) oral doses up to 40 mg would also not be effective, 3) finding an effective oral dose that is also safe is not feasible (meaning that doses higher than 40 mg would need to be explored but would also not be safe to study due to effects on blood pressure), and 4) an appropriate dosing interval for oral PE has not been established (meaning that, based on the PK data, an every-4-hour dosing interval is likely too long).

27. Upon information and belief, Defendants, as manufacturers of the Products, were each aware of the studies suggesting that phenylephrine is ineffective as a nasal decongestant.

CLASS ACTION ALLEGATIONS

28. Plaintiff brings this action pursuant to Fed. R. Civ. P. 23 on behalf of a Class of individuals defined as:

> *All persons in Minnesota who, within the applicable statute of limitations period, purchased an oral nasal decongestant containing phenylephrine manufactured by Kenvue, Inc. and McNeil Consumer Healthcare.*

29. Plaintiff reserves the right to modify or amend the definition of the proposed Class and/or to add subclasses, if necessary, before this Court determines whether class certification is appropriate.

30. Excluded from the Class are: (1) any entity in which Defendants have a controlling interest; (2) officers or directors of Defendants; (3) this Court and any of its employees assigned to work on the case; and (4) all employees of the law firms representing Plaintiff and the Class.

31. This action is brought and may be properly maintained on behalf of each Class member.

32. *Numerosity of the Class:* The members of the Class are so numerous that a joinder of all members would be impracticable. While the exact number of Class members is presently unknown to Plaintiff, and can only be determined through appropriate discovery, Plaintiff believes the Class is likely to include thousands of members based on the fact Defendants distribute their Products throughout Minnesota.

33. The Class definition identifies unnamed Plaintiffs by describing a set of common characteristics sufficient to allow a member of that group to identify themselves as having a right to recover damages from Defendants. Other than by direct notice by mail or email, alternatively proper and sufficient notice of this action may be provided to the Class through notice published in newspapers or other publications.

34. *Commonality:* This action involves common questions of law and fact. The questions of law and fact common to both Plaintiff and the Class include, but are not limited to, the following:

a. Whether Defendants knew that phenylephrine was ineffective as a decongestant;

b. When Defendants knew that phenylephrine was ineffective as a decongestant;

c. Whether Defendants marketed and sold the Products as an effective decongestant;

d. Whether Defendants concealed the ineffective nature of the Products;

e. Whether Defendants had a duty to disclose the ineffective nature of the Products;

f. Whether Defendants' conduct constitutes unfair or deceptive acts or practices under Minnesota law;

g. Whether Defendants were unjustly enriched by the sale of the Products;

h. The appropriate nature of class-wide equitable relief; and

i. The proper method or methods to determine and measure Plaintiff's and the Class' damages.

35. *Typicality:* Plaintiff's claims are typical of all members of the Class. The evidence and the legal theories regarding Defendants' alleged wrongful conduct committed against Plaintiff and the Class are substantially the same because all putative Class members purchased Defendants' Products for personal use and all putative Class members overpaid for the Products. Accordingly, in pursuing her own self-interest in litigating their claims, Plaintiff will also serve the interests of the Class.

36. *Adequacy:* Plaintiff will fairly and adequately protect the interests of the Class. Plaintiff retained competent counsel experienced in class action litigation to ensure such protection. There are no material conflicts between the claims of the representative Plaintiff and the Class that would make class certification inappropriate. Additionally, Plaintiff's Counsel are competent to advance the interests of the Class having been designated as Lead Counsel or Class Counsel in dozens, if not hundreds, of collective, class, and mass actions. Plaintiff and her Counsel intend to prosecute this action vigorously.

37. *Predominance and Superiority:* The matter is properly maintained as a class action under Fed. R. Civ. P. 23(b)(3) because the common questions of law and fact identified herein, and to be identified through discovery, predominate over questions that may affect only individual Class members. Further, a class action is superior to all other available methods for the fair and efficient adjudication of this matter because the injuries suffered by the individual Class members are relatively small. As such, the expense and burden of individual litigation would make it virtually impossible for Plaintiff and the Class to individually seek redress for Defendants'

wrongful conduct. Even if any individual person or group(s) of the Class could afford individual litigation, it would be unduly burdensome to the courts in which the individual litigation would proceed. The class action device is preferable to individual litigation because it provides the benefits of unitary adjudication, economies of scale, and comprehensive adjudication by a single court. In contrast, the prosecution of separate actions by individual Class members would create a risk of inconsistent or varying adjudications with respect to individual Class members that would establish incompatible standards of conduct for the party (or parties) opposing the Class and would lead to repetitious trials of the numerous common questions of law and fact. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action. As a result, a class action is superior to other available methods for the fair and efficient adjudication of this action. Absent a class action, Plaintiff and the Class will continue to suffer losses, thereby allowing Defendants' violations of law to proceed without remedy and allowing Defendants to retain the proceeds of their ill-gotten gains.

38. Plaintiff anticipates the issuance of notice setting forth the subject and nature of the instant action to the proposed Class. To the extent any further notices may be required, Plaintiff anticipates the use of additional media or mailings.

CAUSES OF ACTION

COUNT I

BREACH OF THE IMPLIED WARRANTY OF MERCHANTABILITY

(On Behalf of Plaintiff and the Minnesota Class)

39. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

40. Defendants are merchants engaging in the sale of goods to Plaintiff and the Class.

41. There was a sale of goods from Defendants to Plaintiff and the Class.

42. By operation of law, Defendants, as manufacturer of the Products, impliedly warranted to Plaintiff and the Class that the Products were of merchantable quality and fit for their ordinary and intended use pursuant to Minn. Stat. § 336.2-314;

43. Defendants knew or should have known that its Products were not an effective nasal decongestant. Yet, Defendants repeatedly advertised, both on the Products labels, on their websites, through national advertising campaigns, among other methods, that their Products were an effective nasal decongestant. Defendants did not disclose to Plaintiff and the Class that their Products were not an effective nasal decongestant.

44. Defendants breached the implied warranty of merchantability in connection with the sale and distribution of the Products. At the point of sale, the Products contained labeling showing the Products were intended to treat nasal congestion. These Products were labeled and advertised to benefit consumers like Plaintiff and the Class suffering from nasal congestion.

45. Plaintiff and the Class relied on these implied warranties when they purchased the Products.

46. If Plaintiff and the Class knew that the Products were not of merchantable quality and fit for their ordinary and intended use as a nasal decongestant, then Plaintiff and the Class would not have purchased the Products or would have paid less for them.

47. As a direct and proximate result of Defendants' breach of the implied warranty of merchantability, Plaintiff and the Class have sustained damages in an amount to be determined at trial.

COUNT II

FRAUD BY OMISSION

(On Behalf of Plaintiff and the Minnesota Class)

48. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

49. Defendants knew or should have known the Products were ineffective nasal decongestants.

50. Plaintiff, the Class, and Defendant acted within the context of a business transaction when Plaintiff and the Class purchased Defendants' Products for household or business use, and not for resale.

51. Plaintiff and the Class were ordinary non-business consumers.

52. Defendants actively and knowingly concealed from and failed to disclose to Plaintiff and the Class that the Products were an ineffective nasal decongestant.

53. As pharmaceutical manufacturers, Defendants are in a special position of trust upon which consumers rely.

54. Defendants were under the duty to disclose to Plaintiff and the Class the true quality, characteristics, ingredients, and suitability of the Products because Defendants were in a superior position to know the true state of the facts about their Products and because Defendants knew Plaintiff and the Class could not reasonably have been expected to learn about the omissions without Defendants disclosing the material facts on the Products' packaging or in other media.

55. Defendants know that consumers like Plaintiff and the Class trust the quality of their Products and expect the Products to perform as advertised.

56. Due to the omissions on the Products' packaging and other media, Defendants had a duty to disclose the whole truth about the ineffectiveness of its Products at treating nasal congestion.

57. Defendants acted in bad faith when they intended that Plaintiff and the Class would rely on the omissions when purchasing the Products unaware of the undisclosed material facts.

58. Defendants were under a duty to disclose the omissions because Defendants undertook disclosure of information about the Products on the Products' packaging and in other media.

59. Defendants failed to discharge their duty to disclose the omissions.

60. Defendants allowed the omissions on the Products' packaging to intentionally mislead consumers like Plaintiff and the Class.

61. The facts concealed, omitted, or not disclosed by Defendants to Plaintiff and the Class are material in that a reasonable consumer would have considered the omissions material when deciding whether to purchase the Products.

62. Defendants knew or should have known the omissions were material to the decisions by Plaintiff and the Class to purchase the Products and would induce Plaintiff and the Class to purchase the Products.

63. Defendants intentionally concealed the ineffectiveness of their Products with the intent to defraud and deceive Plaintiff and the Class.

64. Plaintiff and the Class justifiably relied on Defendants' omissions to their detriment. The detriment is evident from the true quality, characteristics, and ingredients of the Products, which is misleading when compared to the Products' packaging and represented by Defendants and inherently unfair to consumers of the Products like Plaintiff and the Class.

65. As a direct and proximate result of Defendant's conduct, Plaintiff and the Class suffered actual damages because they would not have purchased the Products or would have paid less for them if they had known the material facts omitted by Defendants.

66. Plaintiff and the Class seek actual damages, injunctive and declaratory relief, attorneys' fees, costs, and any other just and proper relief available.

COUNT III

UNJUST ENRICHMENT

(On Behalf of Plaintiff and the Minnesota Class)

67. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

68. Plaintiff and the Class conferred a tangible and material economic benefit upon Defendants by purchasing the Products.

69. Plaintiff and the Class would not have purchased the Products or would have paid less for the Products if they had known that the Products were ineffective as a nasal decongestant.

70. Under these circumstances, it would be unjust and inequitable for Defendants to retain the economic benefits they received at the expense of Plaintiff and the Class.

71. Failing to require Defendants to provide remuneration under these circumstances would result in Defendants being unjustly enriched at the expense of Plaintiff and the Class who received no benefit or reduced benefit from the Products because the Products did not work as advertised.

72. Defendants' retention of the benefit conferred upon them by Plaintiff and the Class would be unjust and inequitable.

73. Plaintiff and the Class suffered damages in an amount to be determined at trial.

COUNT IV

VIOLATION OF THE MINNESOTA PREVENTION OF CONSUMER FRAUD ACT

(On Behalf of Plaintiff and the Minnesota Class)

74. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

75. Minnesota's private attorney general statute authorizes consumers to bring a civil action under the CFA and "recover damages, together with costs and disbursements, including costs of investigation and reasonable attorney's fees" and other equitable relief as determined by the court. Minn. Stat. § 8.31, subd. 3a.

76. The CFA permits a consumer to bring a civil action against:

> [t]he act, use, or employment by any person of any fraud, false pretense, false promise, misrepresentation, misleading statement or deceptive practice, with the intent that others rely thereon in connection with the sale of any merchandise, whether or not any person has in fact been misled, deceived, or damaged thereby

Minn. Stat. § 325F.69, subd. 1.

77. Plaintiff, the Class, and Defendants constitute a "person" pursuant to Minn. Stat. § 325F.68, subd. 3.

78. Defendants' Products constitute "merchandise" pursuant to Minn. Stat. § 325F.68, subd. 2.

79. Defendants used fraud, misrepresentations, misleading statements, deceptive practices, and false promises in perpetrating their scheme as alleged herein.

80. Plaintiff and the Class relied upon misrepresentations, misleading statements, deceptive practices, and false promises by Defendants, which resulted in injury to them.

81. Plaintiff and the Class have suffered an ascertainable loss of money because of the use or employment by Defendants of a method, act or practice prohibited or declared to be unlawful by the provisions of the CFA.

82. Plaintiff and the Class' actual out-of-pocket loss was proximately caused by Defendants' violation of the CFA.

83. The circumstances suggest that evidence is likely to exist of the same type of conduct affecting other Minnesota consumers involving Defendants after a reasonable opportunity for further investigation and discovery.

COUNT V

VIOLATION OF THE MINNESOTA UNIFORM DECEPTIVE TRADE PRACTICES ACT ("DTPA")

(On Behalf of Plaintiff and the Minnesota Class)

84. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

85. Defendants' policy and practice of manufacturing and selling the Products as alleged herein is a violation of the DTPA, including by not limited to:

> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
>
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;
>
> (7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
>
> (9) advertises goods or services with intent not to sell them as advertised;
>
> (13) engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

Minn. Stat. § 325D.44, subd. 1.

86. Plaintiff need not prove competition between the parties or actual confusion or misunderstanding. Minn. Stat. § 325D.44, subd. 2.

87. A person likely to be damaged by a deceptive trade practice of another may be granted an injunction against it under the principles of equity and on terms that the court considers reasonable. Proof of monetary damage, loss of profits, or intent to deceive is not required. Minn. Stat. § 325D.45, subd. 1.

88. Should Plaintiff prevail in this Action, reasonable attorneys' fees and costs are to be awarded pursuant to § 325D.45, subd. 2.

COUNT VI

VIOLATION OF THE MINNESOTA FALSE STATEMENTS IN ADVERTISING ACT ("FSAA")

(On Behalf of Plaintiff and the Minnesota Class)

89. Plaintiff re-alleges and incorporates by reference each of the foregoing paragraphs as if fully set forth herein.

90. Minn. Stat. § 325F.67 provides in relevant part:

91. Defendants violated Minn. Stat. § 325F.67 by publicly misrepresenting the effectiveness of its Products in treating nasal congestion, when in fact, it does not treat nasal congestion.

92. Defendants made false representations and untrue statements about the effectiveness of their Products on their website, product packaging, marketing literature, and through representations made by their business representatives and third-party online retailers.

93. Defendants' misrepresentations were material because they related to facts that would naturally affect the purchaser's decision to purchase the product at issue and that a reasonable person, including Plaintiff and the Class, would have considered important in deciding whether to purchase Defendants' Products.

94. Pursuant to Minn. Stat. Minn. Stat. § 8.31, subd. 3a, Plaintiff and the Class may pursue a private cause of action based on Defendants' violation of § 325F.67.

95. The vindication of Plaintiff's claims and the claims of the Class will benefit the public at large.

96. Plaintiff and the Class have suffered damages and monetary loss as a result of Defendants' false, deceptive, and misleading advertising.

97. Plaintiff and the Class suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of the Class, demands a jury trial on all claims so triable and judgment as follows:

A. Certifying the proposed Minnesota Class, appointing Plaintiff as representative of the Minnesota Class, and appointing counsel for Plaintiff as Lead Counsel for the Minnesota Class;

B. Awarding all actual, general, special, incidental, punitive, and consequential damages to which Plaintiff and the Class are entitled;

C. Awarding pre- and post-judgment interest at the maximum rate permitted by applicable law;

D. Reimbursing all costs, expenses, and disbursements accrued by Plaintiff in connection with this action, including reasonable attorneys' fees, costs, and expenses pursuant to applicable law and any other basis; and

E. Awarding such other relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff, individually and on behalf of the Class, hereby demands a trial by jury on all issues in this Class Action Complaint that are so triable.

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Dated: September 15, 2023

Respectfully submitted,

/s/ Jacob R. Rusch

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